



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Examiner Named

Inventor : Matthew S. Reimink

Appln. No.: 09/475,721

Filed : December 30, 1999

For : MEDICAL DEVICES WITH
POLYMER/INORGANIC SUBSTRATE
COMPOSITES

Docket No.: S16.12-0094

Appeal No. ---

Group Art Unit: 1772

Examiner: Sow Fun Hon

**TRANSMITTAL OF APPEAL BRIEF
(PATENT APPLICATION - 37 C.F.R. §41.37)**

Mail Stop Appeal Brief - Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

I HEREBY CERTIFY THAT THIS PAPER
IS BEING SENT BY U.S. MAIL, FIRST
CLASS, TO THE COMMISSIONER FOR
PATENTS, P.O. BOX 1450, ALEXANDRIA,
VA 22313-1450, THIS

18 DAY OF June,
2007.
Hallie A. Finucane
PATENT ATTORNEY

Sir:

Transmitted herewith is the Appeal Brief in this application with respect to the Notice of Appeal filed on April 16, 2007.

FEE FOR FILING APPEAL BRIEF

Pursuant to 37 C.F.R. §41.20(b)(2) the fee for filing the Appeal Brief is \$500.00.

The Director is authorized to charge any additional fees associated with this paper or credit any overpayment to Deposit Account No. 23-1123. A duplicate copy of this communication is enclosed.

Respectfully submitted,

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18 DAY OF June, 2007.
Hallie A. Finucane
PATENT ATTORNEY

Dear Sir:

This is an appeal from an Office Action mailed on December 14, 2006 in
which claims 1-3, 5-20, 31 and 32 were finally rejected.

06/22/2007 HDESTA1 00000002 09475721

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I. REAL PARTY OF INTEREST

The Real Party of Interest, St. Jude Medical, Inc., a corporation organized under the laws of the state of Minnesota, and having offices at One Lillehei Plaza, St. Paul, MN 55117, has acquired the entire right, title and interest in and to the invention, the application, and any and all patents to be obtained therefor, as set forth in the Assignment filed with the patent application and recorded on Reel 010484, Frame 0305.

II. RELATED APPEALS AND INTERFERENCES

None.

III. STATUS OF CLAIMS

- I. Total number of claims in the application.
- Claims in the application are: 1-32
- II. Status of all the claims.
- A. Claims cancelled: 4 and 21-30
- B. Claims withdrawn but not cancelled: None
- C. Claims pending: 1-3, 5-20, 31 and 32
- D. Claims allowed: None
- E. Claims rejected: 1-3, 5-20, 31 and 32
- F. Claims Objected to: None
- III. Claims on appeal
- The claims on appeal are: 1-3, 5-20, 31 and 32

IV. STATUS OF AMENDMENTS

No amendment was filed subsequent to the final rejection.

V. SUMMARY OF THE CLAIMED SUBJECT MATTER

The Appellant's invention in independent claim 1 is directed to a medical device comprising a composite. (Page 4, lines 15-16, page 8, lines 22-30, and Figures 1-6). The composite has an inorganic substrate and a polymer applied on all of the substrate surfaces. (Page 4, lines 15-19, page 5, lines 20-23, page 6, lines 5-8, page 14, lines 4-8, and page 16, lines 29-31). The polymer forms a structure that is shaped differently from the structure of the substrate, and provides the form of the device. (Page 4, lines 25-29, page 6, lines 27-29, page 16, lines 3-6, page 6, line 34-page 17, line 4, and page 19, lines 30-33).

The Appellant's invention in independent claim 10 is directed to a medical device that comprises a flexible composite component comprising an inorganic substrate and a polymer member covering the substrate. (Page 4, lines 15-25, and 30-31, page 6, lines 5-6, page 6, line 30-page 7, line 7, page 8, lines 22-30, page 14, lines 4-8 and 24-25, page 15, lines 27-31, page 18, lines 15-25, and Figures 3, 4, 5A, 6). The flexible component can be bent through a cross section of the flexible component composite. (Page 19, lines 3-20, FIG. 4). The polymer member contacts bodily fluids and separates the bodily fluids from the substrate. (Page 4, lines 32-33, page 6, lines 8-16, and page 17, lines 3-5).

VI. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

- A. Whether claims 1-3, 8 and 9 are properly rejected as being anticipated by Reul et al. U.S. Patent No. 4,263,680 ("Reul patent").
- B. Whether claims 5-7, 31 and 32 are properly rejected as being obvious over the Reul patent in view of Pietsch U.S. Patent No. 4,778,461 ("Pietsch patent").
- C. Whether claims 10, 11 and 16-19 are properly rejected as being anticipated by the Reul patent.
- D. Whether claims 12-14 are properly rejected as being obvious over the Reul patent in view of the Pietsch patent.
- E. Whether claim 15 is properly rejected being obvious over the Reul patent in view of the Pietsch patent and in view of Lenkei U.S. Patent No. 4,597,767 ("Lenkei patent").
- F. Whether claim 20 is properly rejected as being obvious over the Reul patent in view of Sumitomo Electric Co. Japan Abstract 59192366.

VII. ARGUMENT

A. The Office Action Erred in Alleging that Claims 1-3, 8 and 9 are Anticipated by the Reul Patent.

The Office Action erroneously rejected independent claim 1 as being anticipated by the Reul patent. The Office Action alleges that the Reul Patent discloses a medical device (prosthetic heart valve at col. 6, line 29) that comprises a composite (valve member 1, col. 5, line 41) having an inorganic substrate (metal substrate 12, col. 5, lines 45-47) and a polymer applied on all of the substrate surfaces (blood compatible synthetic material 14, col. 5, lines 41-44). The Office Action erroneously alleges that the polymer forms a structure shaped differently from the structure of the substrate and provides a form of the device (FIG. 3, hinge flap is formed in one piece with the valve member) and consists of the same blood-compatible synthetic material with which the valve member is coated, integrally cast in the course of the coating process (col. 4, lines 39-45). The Office Action alleges that the valve ring is coated with the same blood-compatible synthetic material as the valve member at col. 4, lines 47-49. In the Response to Arguments section, the Office Action makes reference to FIG. 3 of the Reul Patent and erroneously alleges that the composite 1 has the shape of a dish which is different from the shape of the inorganic substrate 12.

Appellant submits that the Office Action erred in alleging that independent claim 1 is anticipated by the Reul Patent. An element of independent claim 1 includes an inorganic substrate with a polymer applied on all of the substrate surfaces, the polymer forming a structure that is shaped differently from the structure of the substrate, and providing the form of the device.

Contrary to the allegations contained in the Office Action, the Reul Patent does not disclose the application of a polymer on all substrate surfaces where the polymer forms a structure shaped differently from the structure of the substrate. Referring to col. 4, lines 23-25, the Reul Patent discloses using a dipping process to coat the biocompatible onto the inorganic substrate.

A dipping process places a layer having a substantially uniform thickness onto the inorganic substrate that conforms to the general shape of the substrate. A polymer

coating of a substantially uniform thickness does not provide a structure that is shaped differently from the structure of the substrate as claimed. Rather, the synthetic material coating disclosed in the Reul Patent conforms to the shape of the substrate.

The Office Action makes reference to FIG. 3 which is a cross-section of the valve member taken along section line III-III in FIG. 1. FIG. 3 illustrates a portion of the substrate having an aperture therethrough which, according to the Reul Patent, enables the layers of synthetic material on each side of the metal substrate to be interconnected. In the finished valve member, these apertures are completely filled with synthetic material. See col. 5, lines 48-53. Interconnections created by filling in the voids created by the apertures between the outer surfaces of the valve member do not affect the form of the device as claimed. The synthetic material coating still conforms to the shape of the substrate.

Referring to FIG. 2 of the Reul patent, the outer surface of the polymer on valve member 1 has the same configuration as the outer surface of the metal substrate 12. It is clearly shown that the metal substrate is in the form of a cupped disc and that the polymeric material follows the form of the metal substrate, also forming a cupped disc.

The Examiner also alleged that the hinge flap disclosed in the Reul patent is an anchor as disclosed in Appellant's specification in the Response to Request for Reconsideration. Figure 1 shows the hinge 4 as being internal to the construction of the heart valve. Hinge 4 is not shown in the cross section shown in Figure 2. The Examiner has failed to provide any evidence showing that the hinge provides a form to the device as claimed. Therefore, the hinge cannot provide a form of the device as claimed.

For the foregoing reasons the Office Action erred in rejecting independent claim 1 as being anticipated by the Reul patent. Reversal of the rejection of claim 1 is respectfully requested.

The Office Action also erroneously rejected claims 2, 3, 8 and 9 as being anticipated by the Reul patent. While Appellant does not acquiesce to the rejections of claims 2, 3, 8 and 9, the rejections are improper because independent claim 1 is not anticipated by the Reul patent. Reversal of the rejections of claims 2, 3, 8 and 9 is respectfully requested.

B. The Office Action Erred in Alleging That Claims 5-7, 31 and 32 Obvious over the Reul patent in view of the Pietsch Patent.

The Office Action erred in alleging that claims 5-7, 31 and 32 are obvious over the Reul patent in view of the Pietsch patent. While Appellant does not acquiesce to the rejections of dependent claims 5-7, 31 and 32, the rejections are improper because independent claim 1 is in allowable form. Reversal of the rejections of claims 5-7, 31 and 32 is respectfully requested.

C. The Office Action Erred in Alleging that Claims 10, 11 and 16-19 are Anticipated by the Reul Patent.

The Office Action erroneously rejected independent claim 10 under 35 U.S.C. § 102(b) as being anticipated by the Reul Patent. The Office Action erroneously alleges that the Reul Patent discloses a medical device which is a prosthetic heart valve (col. 6, line 29,) which comprises a composite component having an inorganic substrate (metal substrate 12, col. 5, lines 45-47) and a polymer member covering the substrate (blood-compatible synthetic material 14, col. 5, lines 41-44) where the composite component can be bent through a cross-section of the composite component (thin valve member including metal substrate can be bent, 0.3 to 0.4 mm, col. 3, lines 40-45) and wherein the polymer member contacts bodily fluid and separates the bodily fluid from the substrate (blood-compatible synthetic material, col. 4, lines 40-45). The Office Action erroneously alleges that the composite component is flexible by virtue of its thickness (less than 0.3-0.4 mm, col. 3, lines 40-42) and its composition (thin metal substrate, col. 5, lines 45-46) and coating of blood-compatible synthetic material (col. 5, lines 41-44,) which is flexible, flap made from the same (col. 6, lines 44-46, col. 4, lines 39-45).

Appellant respectfully disagrees that independent claim 10 is anticipated by the Reul Patent. An element of independent claim 10 includes a flexible composite component comprising an inorganic substrate and polymer member covering the substrate, wherein the flexible composite component can be bent through a cross-section of the flexible component composite.

There is no disclosure that the Reul Patent discloses a heart valve member that can be bent through a cross-section. The Office Action alleges that because the valve member has a thickness of 0.3-0.4 mm, it must inherently flex. However, there is no disclosure that the heart valve member would flex. Further, a valve member that flexes would make the valve member less responsive in its opening and closing function which is in direct contrast to the advantages stated of the valve member as stated in the Reul Patent.

This has the advantage that, compared to traditional valves, very short opening and closing times can be achieved, since the moment of inertia of the thin dish is very small in comparison with spherical or disc valves. This fact guarantees that the valve can react almost instantaneously to the quickly changing pressure gradients inside the heart chamber and thus resembles a natural valve more closely than any other existing artificial heart valve. Col. 3, lines 42-58.

A reduction in weight of the valve member to decrease the moment of inertia does not lead to the conclusion that the valve member flexes. If the valve member flexed, some of the force created by the pressure gradient would have to be directed into forcing the valve member to flex, thereby decreasing the responsiveness of the valve to the pressure gradient. The decreased responsiveness is due to it being a two-step process: first flexing the valve member and then moving the valve member about a pivot. This is contrary to the responsiveness teachings of the Reul Patent, above. As such, there is no teaching in the Reul Patent that the valve member for an artificial heart valve flexes.

Further, Appellant does not understand the statement in the Office Action that it is common knowledge that a natural valve is flexible as evidenced by U.S. Pat. No. 4,888,009 and U.S. Pat. No. 5,500,016. The cited passage at col. 3, lines 42-58 relates to the performance of the valve disclosed in the Reul patent in comparison to other heart valves and a natural heart valve. The cited passage does not relate to the structure of the valve.

There is no disclosure that the heart valve disclosed in the Reul patent flexes as it has a substantially different structure than a natural heart valve and opens and closes in a substantially different manner than a natural heart valve.

A natural heart valve has a distinctly different structure than the heart valve in the Reul Patent. Referring to page 591 of Dorland's Illustrated Medical Dictionary, 23rd Edition, the heart valve has leaflets having edges that move away and contact each other to allow blood to flow through and not backflow. A copy of p. 591 of Dorland's Illustrated Medical Dictionary, 23rd Edition, is attached hereto as Exhibit A. Each of the leaflets in a natural heart valve must flex in order to open and close the valve.

However, the valve in the Reul Patent does not have the structure of a natural heart valve. Rather, the valve of the Reul patent has a cup-shaped disc configuration that is hingedly attached to a vessel wall at one end. The flexing of this cup-shaped valve would reduce the response time of the valve and hinder its performance.

Further, Appellants do not understand the Office Action's inherency argument especially in light of the fact that a member that flexes would consume energy that would normally be used to move the cupped valve about its hinge, which is in direct contradiction to the disclosure of the Reul patent. To allege inherency, the Examiner must meet the burden of proof that what is asserted must necessarily happen. See MPEP § 2112.

The inherent teaching of a prior art reference is a question of fact that arises both in the context of anticipation and obviousness. *In re Napier*, 55 F.3d 610, 613, 34 USPQ2d 1782, 1784 (Fed. Cir. 1995). The fact that a certain result or characteristic may occur or be present in the prior art is not sufficient to establish the inherency of that result or characteristic. *In re Rijckaert*, 9 F.3d 1531, 1534, 28 USPQ2d 1955, 1957 (Fed. Cir. 1993) "To establish inherency, the extrinsic evidence 'must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill. Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient.'" *In re Robertson*, 169 F.3d 743, 745, 49 USPQ2d 1949, 1950-51 (Fed. Cir. 1999). "In relying upon the theory of inherency, the Examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art." *Ex parte Levy*, 17 USPQ2d 1461, 1464 (Bd. Pat. App. & Inter. 1990).

The Examiner has provided no evidence that the cup-shaped valve as disclosed in the Reul Patent must inherently flex. Rather, in contrast, the Reul Patent discloses that it would be disadvantageous for the valve to have flexing capabilities. Therefore, the Examiner has not met the burden in alleging inherency.

For the foregoing reasons, the Office Action erred in alleging that claim 10 is anticipated by the Reul patent. Reversal of the rejection of claim 10 is respectfully requested.

The Office Action also erroneously rejected claims 11 and 16-19 as being anticipated by the Reul patent. While Appellant does not acquiesce to the rejections of dependent claims 11 and 16-19, the rejections are erroneous in light of the fact that independent claim 10 is in allowable form. Reversal of the rejections of claims 11 and 16-19 is respectfully requested.

D. The Office Action Erred in Rejecting Claims 12-14 as being Obvious Over the Reul Patent in view of the Pietsch Patent.

The Office Action erroneously rejected claims 12-14 as being obvious over the Reul patent in view of the Pietsch patent. While Appellant does not acquiesce to the rejections of dependent claims 12-14, the rejections are improper because independent claim 10 is in allowable form. Reversal of the rejections of claims 12-14 is respectfully requested.

E. The Office Action Erred in Rejecting Claims 15 as being Obvious Over the Reul Patent in view of the Pietsch Patent and in view of the Lenkei Patent.

The Office Action erroneously rejected claim 15 as being obvious over the Reul patent in view of the Pietsch patent and in view of the Lenkei patent. While Appellant does not acquiesce to the rejection of dependent claim 15, the rejection is improper because independent claim 10 is in allowable form. Reversal of the rejection of claim 15 is respectfully requested.

F. The Office Action Erred in Rejecting Claims 20 as being Obvious Over the Reul Patent in view of Sumitomo Electric Co. Japan Abstract 59192366.

The Office Action erroneously rejected claim 20 as being obvious over the Reul patent in view of Sumitomo Electric Co. Japan Abstract 59192366. While Appellant does not acquiesce to the rejection of dependent claim 20, the rejection is improper because independent claim 10 is in allowable form. Reversal of the rejection of claim 20 is respectfully requested.

Conclusion

Appellant respectfully submits that claims 1-3, 5-20, 31 and 32 are patentable over the cited prior art. It is respectfully requested that the rejections be reversed, and that all pending claims be allowed.

Respectfully submitted,

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Appendix A**CLAIMS INVOLVED IN APPEAL:**

1. A medical device comprising a composite having an inorganic substrate and a polymer applied on all of the substrate surfaces, the polymer forming a structure shaped differently from the structure of the substrate, and providing the form of the device.
2. The medical device of claim 1 wherein the inorganic substrate comprises metal.
3. The medical device of claim 1 wherein the inorganic substrate comprises a ceramic.
5. The medical device of claim 1 wherein the polymer is selected from the group consisting of polyetheretherketones, polyacetals, polyethersulfones, polyarylsulfones, polyetherimides, polycarbonates, and polysulfones.
6. The medical device of claim 1 wherein the polymer has an average thickness of at least about 10 microns.
7. The medical device of claim 1 wherein the polymer has an average thickness from about 100 microns to about 2000 microns.

8. The medical device of claim 1 wherein the medical device comprises a heart valve prosthesis, the heart valve prosthesis comprising a component that comprises the composite having the inorganic substrate and the polymer material.
9. The medical device of claim 1 wherein the polymer material has structure forming a slot, hole, pin, button, barb or anchor.
10. A medical device comprising a flexible composite component comprising an inorganic substrate and a polymer member covering the substrate, wherein the flexible composite component can be bent through a cross section of the flexible component composite, and wherein the polymer member contacts bodily fluids and separates the bodily fluids from the substrate.
11. The medical device of claim 10 wherein the inorganic substrate comprises a metal foil with a thickness less than about 500 microns.
12. The medical device of claim 10 wherein the polymer is selected from the group consisting of polyurethanes, polydimethylsiloxanes and polytetrafluoroethylenes.
13. The medical device of claim 10 wherein the polymer member has a thickness from about 10 microns to about 500 microns.
14. The medical device of claim 10 wherein the polymer member has a thickness from about 50 microns to about 300 microns.

15. The medical device of claim 10 wherein the medical device comprises a heart valve prosthesis and the composite component comprises leaflets.
16. The medical device of claim 10 wherein the flexible composite component can be bent about 180 degrees without extending the flexible composite component beyond its elastic limit.
17. The medical device of claim 10 wherein the flexible composite component can be bent about 180 degrees with a radius of curvature of about the thickness of the composite without extending the flexible composite component beyond its elastic limit.
18. The medical device of claim 10 wherein the flexible composite component can be bent about 60 degrees for about 40 million cycles without significant structural failure.
19. The medical device of claim 10 wherein the flexible composite component can be bent about 60 degrees for about 400 million cycles without significant structural failure.
20. The medical device of claim 10 further comprising a diamond-like carbon coating over at least a portion of the polymer member.
31. The medical device of claim 1 wherein the polymer is crosslinked.
32. The medical device of claim 1 wherein the polymer is rigid.

Appendix B

Evidence Index

Appellant has submitted no evidence under 37 C.F.R. §§ 1.130, 1.131 or 1.132 through the prosecution of this application.

Appendix C

Related Proceedings Index

None.

heat

heart

Exhibit A

t from excessive beer drinking. ricular heart block. **wander-**ally movable heart. **wooden-**which is enlarged to the left with is seen in the roentgen ray film. 'blok). The condition in which connection between the auricle iculoventricular band or band ed, so that the auricle and ven- dently of each other (Gaskell). arked by permanent or parox- , epileptiform, vertiginous, or and pulsations of the cervical rate those of the arteries. The as **Adams-Stokes disease**. **ar-**form in which there is inter- fine terminal subendocardial e system. The electrocardio- asic curve absent and a nega- a splintered R wave present. **r h., auriculoventricular** the blocking is at the auriculo- n. **bundle-branch h., in-**complete h., a condition in al relation between the parts is is destroyed by a lesion, so d ventricles act independently **triventricular h.,** a form in : contracts without the other uction in one of the branches is; called also **bundle-branch ular h.,** a form in which the between the auricles and the : veins and coronary sinus. n). A burning sensation in the

'fál-yer). 1. Sudden fatal ces- action. 2. The clinical con- inability of the myocardium maintain an adequate flow of es of the body. **backward** y passive engorgement of the d by a backward rise in pres- heart. **congestive h.,** pro- of the ability of the heart to e flow of blood to the tissues. uction in the amount of blood rd direction by the heart, re- e supply of blood to the tis- ular h., failure of proper atricle, with dyspnea, orthop- 'entricular h., failure of of the right ventricle, with , hepatic enlargement, and

-om'e-ter). An instrument ed sphygmotograph and

it'er). A fatal disease of cat- marked by fluid accumula- icardium and pleural cavity. *dria ruminantium*, which is ticks *Amblyomma hebraeum*

m). *Dirofilaria immitis*.

ir. *thermē*). 1. The sensation mperature. 2. The energy ansation of heat. It exists in r or atomic vibration (ther- y be transferred by conduc- ce, by convection by a sub- on as electromagnetic waves. animals. **atomic h.,** the red to raise an atom from 0 ve h., heat applied to the om a heated object, such as **nvective h.,** heat thrown he body from some outside erapy, heating of the body the visible and infra-red m. **conversive h.,** heat the tissues by the resistance passage of high-frequency . **delayed h.,** recovery

